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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER ARCHIE, NINA	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 01/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,600	Applicant(s) HAMIDI ET AL.	
	Examiner Nina A. Archie	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,19 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,19,21,23-29, and 31-36 is/are rejected.
- 7) ☒ Claim(s) 22 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 10-10-07. Claims 7-8, and 19-36 are pending. Claims 7-8 and 19 have been amended. Claims 1-6, 9-18, and 20 have been cancelled. Claims 21-36 are new claims.

Objections/Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections are withdrawn.

- a) Objection to claim 6, page 2 is withdrawn in light of cancellation of the claim.
- b) Rejections of claims 6-8 and 19 under 35 U.S.C. 112, second paragraph, page 3 last paragraph is withdrawn in light of applicant's amendment thereto and cancellation of the claims.
- c) Rejection of claims 7-8 and 19 under 35 U.S.C. 102 (b), page 4 is withdrawn in light of applicant's amendment thereto, applicant's argument, and cancellation of claims.
- d) Rejection of claims 7 under 35 U.S.C. 102 (b), page 5 is withdrawn in light of applicant's amendment thereto, applicant's argument, and cancellation of claims.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 7-8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling and the rejection is maintained for the reasons set forth in the previous office action.

Applicant arguments:

The Official Action asserts that claim 6 lacks essential subject matter and omits essential steps. However, claim 6 has been canceled and its subject matter has been incorporated into newly independent claim 7. Instant claim 7 sets forth sufficient subject matter set forth in definite method steps. Claim 7 (and its dependent claims) is thus enabled and contains subject matter set forth in a way that is clear, definite and has full antecedent basis.

Examiner's Response to Applicant's Arguments:

Examiner accepts the amendments to claim. However, the claim is drawn to a method for recovering a polysaccharide from a fermentation broth comprising: omitting the use of centrifugation, ultracentrifugation and chromatography; maximally 4 precipitation steps. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Furthermore, claim 7 and 19 recites "chromatography", as to the limitation of chromatography, there are multiple forms of chromatography therefore it is unclear as to which chromatography method Applicant is referring to.

As outlined previously, the instant claims are drawn to claims 7-8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The claim is drawn to a method for recovering a polysaccharide from a fermentation broth comprising: omitting the use of centrifugation, ultracentrifugation and chromatography; maximally 4 precipitation steps. Critical or essential subject matter to the practice of the invention is not included in claim 6 and therefore is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). For example the precipitation steps are not described therefore the method steps are unclear of how to recover a polysaccharide from a fermentation broth. Furthermore, claim 6 recites "chromatography", as to the limitation of chromatography, there are multiple forms of chromatography therefore it is unclear as to which chromatography method Applicant is referring to.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24-26 and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 24-26 and 32-34 recites the phrase of final concentrations of "60-74 % w/v, 10-50 % w/v, and 60-85% w/v". Although Applicant filed an explanation in the Applicants Arguments/Remarks on 10/10/2007 of final concentrations of "60-74 % w/v, 10-50 % w/v, and 60-85% w/v", there is no support provided in the written description of the specification (see pg. 7, lines 8-15). Therefore, it is apparent, that Applicants were not in possession of the claims 24-26 and 32-34 at the time of filing. Applicants pointing to the specification by page and line number where specific written description for the final concentrations of "60-74 % w/v, 10-50 % w/v, and 60-85% w/v" can be found may resolve this issue.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7-8 and 19, 23, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellwood et al US Patent 5,563,051 Date October 8, 1996.

Claims 7-8 and 19, 23, 31 are drawn to a method for recovering a polysaccharide from a fermentation broth comprising: mixing a polysaccharide fraction with an anionic detergent; and adding alcohol until a concentration is below a concentration necessary

for precipitating the polysaccharide, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography (claim 7); method for recovering a polysaccharide from a fermentation broth comprising: employing a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide fraction; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below a concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate; and dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography (claim 19).

Ellwood et al teach a process for the production of hyaluronic acid (HA) by fermentation (see abstract). Ellwood et al teach that the HA extracted with an aqueous medium containing an anionic surfactant (see column 4 lines 8-20). Ellwood et al teach HA is precipitated by the addition of a non-solvent, for example a lower alcohol such as ethanol. The precipitated HA is filtered off and the filtrate discarded using diafiltration step (see column 4 lines 50-67 and column 5 lines 1-8). Ellwood et al teach the addition of a cationic surfactant as for the HA to be removed by filtration (see column 4 lines 58-67). Therefore the method of Ellwood et al teach a method for recovering a polysaccharide from a fermentation broth comprising: mixing a polysaccharide fraction with an anionic detergent; and adding alcohol until a concentration is below a concentration necessary for precipitating the polysaccharide, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography, further comprising employing a cationic detergent to precipitate the polysaccharide or part of the contaminants from the

supernatant to obtain a polysaccharide fraction; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below the concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration, wherein the alcohol is ethanol (see claim 26).

Therefore the method of Ellwood et al teach a method for recovering a polysaccharide from a fermentation broth comprising: employing a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide fraction; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below a concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate; and dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography, wherein the alcohol is ethanol (see claim 26).

6. Claims 7-8, 19, 21-23, 27-29, 30-31, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellwood et al US Patent 5,563,051 Date October 8, 1996 in view of Hasler et al US Patent 6,891,037 (US Filing Date October 6, 1999), Lander et al US Patent No. 6,410,025 Date June 25, 2002.

Claims 7-8, 19, 21-23, 27-29, 30-31, and 35-36 are drawn to a method for recovering a polysaccharide from a fermentation broth comprising: mixing a

polysaccharide fraction with an anionic detergent; and adding alcohol until a concentration is below a concentration necessary for precipitating the polysaccharide, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography (claim 7); method for recovering a polysaccharide from a fermentation broth comprising: employing a cationic detergent to precipitate the polysaccharide or part of the contaminants from the supernatant to obtain a first polysaccharide fraction; employing alcohol to precipitate the polysaccharide from the first polysaccharide fraction to obtain a second polysaccharide fraction; subjecting the second polysaccharide fraction to an alcohol precipitation in the presence of an anionic detergent, whereby the alcohol is present in the concentration which is below a concentration at which the polysaccharide precipitates; precipitating the polysaccharide from the soluble fraction employing alcohol to obtain a polysaccharide precipitate; and dissolving the polysaccharide precipitate; and dissolving the polysaccharide precipitate and subjecting it to concentration and diafiltration, wherein the method comprises a maximum of 4 precipitation steps, and the method omits employment of phenol, high-speed centrifugation and chromatography (claim 19).

Ellwood et al is relied upon as set forth supra. However, Ellwood et al does not teach a method, wherein the anionic detergent comprises sodium deoxycholate, wherein the cationic surfactant comprises hexadecyltrimethyl ammonium bromide, wherein the polysaccharide is obtained from *Haemophilus influenza* type b.

Hasler et al teach a method for the isolation of polysaccharides, in particular for the separation of endotoxins from capsule polysaccharides of gram-negative bacteria such as *Haemophilus influenzae* (type b) (see abstract, column 2 lines 17-20). Hasler et al teach that the removal of endotoxins is a critical and decisive step during the purification of polysaccharides and the method for the separation of endotoxins from bacterial polysaccharides which is used most often according to the state of the art is based on the extraction with phenol, which, if necessary, has to be repeated several times until the endotoxin content is as required by health authorities (see column 1).

Hasler et al teach a method for the isolation of polysaccharides which is simple, economically useful and less injurious to health thus the invention relates to a method for the isolation of polysaccharides, wherein the following steps are carried out (a) mixing of a bacterial polysaccharide fraction with a detergent solution (anionic detergent); (b) addition of alcohol to a final concentration which is below the concentration at which the polysaccharide precipitates; (c) mixing the solution; (d) filtering the solution; (e) separation of the polysaccharide from detergent and alcohol (see column 1).

Lander et al teach that bacterial polysaccharides are isolated then precipitated with a long chain detergent (see abstract). Lander et al teach that the cationic detergent is cetyltrimethylammonium bromide (CETAB) (hexadecyltrimethyl ammonium bromide) (see column 2). Lander et al teach that by-products, any unreacted derivatized polysaccharide and excess reagents are removed by diafiltration against volumes of deoxycholate (see column 4).

It would have been prima facie obvious at the time the invention was made to use a method as taught by Ellwood et al and to include, wherein the polysaccharide is obtained from Haemophilus influenza type b as taught by Hasler et al because both Ellwood et al and Hasler et al teach isolation of polysaccharides to obtain a purified polysaccharide. It would also have been prima facie obvious at the time the invention was made to use a method as taught by Ellwood et al and to include an anionic detergent comprising sodium deoxycholate and a cationic surfactant comprising hexadecyltrimethyl ammonium bromide as taught by Lander et al because both Ellwood et al and Lander et al teach isolation of polysaccharides to obtain a purified polysaccharide.

Status of the Claims

7. No claims are allowed.

Claims 7, 8, 19, 21, 23-29, and 31-36 are rejected.

Claims 22 and 30 are objected as being dependent from a rejected base claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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Nina A Archie

Examiner

GAU 1645

REM 3B31



MARK NAVARRO
PRIMARY EXAMINER